

REMARKS/ARGUMENTS

In the Election/Restriction requirement dated February 1, 2008, the Examiner delineated the following inventions as being patentably distinct.

Group I:        Claims 1-18 and 20-30, drawn to an oral multiparticulate pharmaceutical from comprising pellets; and

Group II:       Claims 19, 31, and 32, drawn to a process for producing an oral multiparticulate form.

Applicants provisionally elect, with traverse, Group I.

The Examiner further required the election of a single species. Accordingly Applicants provisionally elect, also with traverse, the following:

- 1<sup>st</sup> Cetrorelix as active substance;
- 2<sup>nd</sup> Chitosan as a component of inner matrix;
- 3<sup>rd</sup> Anionic (meth) acrylate copolymer, especially the EUDRAGIT L type as outer coating;
- 4<sup>th</sup> Absence of a separating layer; and
- 5<sup>th</sup> Absence of a bipophilic matrix.

Restriction is only proper if the claims of the restricted groups are independent or patentably distinct and there would be a tenuous burden placed on the Examiner if restriction is not required (M.P.E.P. § 803). The burden of proof is on the Examiner to provide reasons and/or examples to support any conclusions in regard to patentable distinction.

All of the claims are linked with respect to an oral multiparticulate pharmaceutical form and the method for the preparation, that must satisfy certain relationship as recited in the claims that is responsible for the activity, and as such should be examined together on the merits, especially wherein the sole disclosed utility is that recited in the specification.

Different classification of subject matter to be divided is not conclusive proof of independent status and disability there is a commonality that exists between the groups. It is a technical relationship that involves the same feature, and it is this technical feature that defines the contribution which each of the groups taken as a whole makes over the prior art.

Unit of invention has to be considered in the first place only in relation to the independent claim. A dependent claim is one which contains all the features of another claim and is in the same category of claims as the other claims. It does not matter if a dependent claim itself contains a further invention.

Further, M.P.E.P. § 803 states as follows:

If the search and examination of an entire application can be made without a serious burden, the Examiner must examine it on the merits even though it includes claims to distinct and independent inventions.

Applicants submit that a search of all the claims would not constitute a serious burden on the Office.

Applicants request that should the elected species be found allowable, the Examiner must expand the search to include the non-elected inventions.

Divisional applications filed thereafter claiming the non-elected inventions should not be subject to a double-patenting ground of regulation, 35 U.S.C. § 121, *In re Joyce* (Comr. Pat. 1957), 115 USPQ 412.

Applicants submit that the above-identified application is now in condition for examination on the merits, and an early notice of such action is earnestly solicited.

Respectfully submitted,

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